Reference number(s)
5688-A

SPECIALTY GUIDELINE MANAGEMENT

REZLIDHIA (olutasidenib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Relapsed or Refractory Acute Myeloid Leukemia
Rezlidhia is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of isocitrate dehydrogenase-1 (IDH1) mutation

III. CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for treatment as a single agent in members with relapsed or refractory AML with a susceptible IDH1 mutation.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Rezlidhia [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; December 2022.
2. The NCCN Drugs & Biologics Compendium®. © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 4, 2024.